Bioprosthetic plug insertion for anal fistula

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg662

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG410.

1   Recommendations

1.1   Current evidence on the safety and efficacy of bioprosthetic plug insertion for anal fistula is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit. Find out what standard arrangements mean on the NICE interventional procedures guidance page.

1.2   The procedure should only be done by a surgeon experienced in managing anal fistulas.

2   The condition, current treatments and procedure

The condition

2.1   An anal fistula is an abnormal tract between the anal canal and the skin around the anus. It usually results from previous anal abscesses (cryptoglandular) and can be associated with other conditions such as inflammatory bowel disease and cancer. It may cause symptoms such as pain or discomfort in the anal area, and leakage of blood or pus. Anal fistulas can be classified according to their anatomical relationship with the external sphincter. Intersphincteric fistulas are the most common type and cross only the internal sphincter. Trans-sphincteric fistulas pass through the internal and external sphincter.

Current treatments

2.2   Treatment of anal fistulas commonly involves surgery. The type of surgery depends on the location and complexity of the fistula. For intersphincteric and low trans-sphincteric anal fistulas, the most common treatment is a fistulotomy or laying open of the fistula tract. For deeper fistulas that involve more muscle, and for recurrent fistulas, a seton (a piece of suture material or rubber sling) may be used, either alone or with fistulotomy. Setons can be loose (designed to drain the sepsis but not for cure), or snug or tight (designed to cut through the muscles in a slow controlled fashion). Fistulas that cross the external sphincter at a high level are sometimes treated with a mucosal advancement flap or other procedures to close the internal opening. Other options for treating anal fistulas are to fill the tract with glue or paste.

The procedure

2.3   Bioprosthetic plug insertion for anal fistula aims to leave the sphincter muscles intact, allowing the use of subsequent treatments if needed.

2.4   The procedure is usually done using general anaesthesia. The fistula tract is identified using a probe or by imaging techniques, and it may be irrigated. A conical plug, usually made of porcine intestinal submucosa, is pulled into the tract until it blocks the internal opening. It is sutured in place at the internal opening. The external opening is not completely sealed so that drainage of the fistula can continue. The plug acts as a scaffold into which new tissue can grow.

3   Committee considerations

The evidence

3.1   To inform the committee, NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 12 sources, which was discussed by the committee. The evidence

included 3 systematic reviews, 4 randomised controlled trials, 4 case series and 1 unpublished NIHR Health Technology Assessment report on the fistula-in-ano trial (FIAT), and is presented in table 2 of the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2   The specialist advisers and the committee considered the key efficacy outcomes to be: fistula closure, resolution of symptoms, prevention of recurrence and the need for further surgery, and improved quality of life.

3.3   The specialist advisers and the committee considered the key safety outcomes to be: plug extrusion, incontinence, abscess or infection, bleeding, pain and anismus.

3.4   Patient commentary was sought but none was received.

Committee comments

3.5   The committee was informed that the success rate of the procedure is likely to be higher for single tracts and posterior fistulas.

3.6   The evidence reviewed by the committee shows that bioprosthetic plug insertion for anal fistula has a similar safety and efficacy profile to standard treatments for anal fistulas.

3.7   The committee was informed that bioprosthetic plug insertion for anal fistula may be used in combination with other treatments.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.